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CHAPTER 4. DIALYSIS PROGRAM

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part IV, Chapter 4, dated October 23, 1990.

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CHAPTER 4. DIALYSIS PROGRAM

4.01 PURPOSE

The purpose of this chapter is to establish policy and provide guidelines for the operation of the Dialysis Units.

4.02 POLICY

a. Department of Veterans Affairs (VA) will appropriately treat patients with End Stage Renal Disease (ESRD) as indicated by competent professional judgment. This may include conservative therapy, hemodialysis and peritoneal dialysis in a medical facility or at home, and renal transplantation.

b. The extensive professional expertise and other resources necessary to provide proper ESRD care require that designated dialysis units be located and operated for maximum effectiveness and efficiency.

c. Only VA facilities having the approval of the appropriate Regional Director with concurrence of Medical Service, VA Central Office, should undertake chronic dialysis care. No VA medical center with the necessary expertise is barred from performing acute dialysis when medically necessary.

4.03 ELIGIBILITY FOR CARE - GENERAL CONSIDERATIONS

a. Priorities for treatment of patients will conform to established beneficiary priorities for VA hospital care and outpatient care.

b. Within beneficiary priority classes highest priority for dialysis treatment will be given to seriously ill, or unstable patients urgently in need of care, and lowest priority will be given to clinically stable patients receiving ESRD care in a non-VA program who seek elective transfer into a VA program.

(1) Veterans who are nonservice-connected (NSC) for renal disease and who are stable and receiving care in a non-VA program may be accepted for transfer into a VA dialysis unit on a space-available basis in accordance with pertinent eligibility regulations.

(2) Such NSC patients seeking VA care should be informed by the dialysis and/or medical administrative staff that the VA ordinarily will not pay for subsequent care in a non-VA unit (such as if they live too far from a VA medical center having a dialysis program, or if the VA Dialysis Program becomes overtaxed) unless the patient's other resources, such as Medicare, are clearly inadequate to support such treatments.

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(3) Veterans shall not be admitted for the sole purpose of placing them on outpatient nonservice-connected (OPT-NSC) care. (See par. 4.07 for further information on VA support of patients in non-VA dialysis units.)

(4) When a veteran patient is denied acceptance into a VA Dialysis Program because of lack of capability, the VA staff should assist the patient in identifying an alternate source or sources of dialysis treatment.

4.04 PROGRAM COMPONENTS

a. Dialysis Center. A VA medical center designated as a Dialysis Center is capable of providing the full spectrum of dialysis related diagnostic and therapeutic services required by patients with end stage renal disease:

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(1) Each VA Dialysis Center will have appropriate arrangements for evaluating patients as transplantation candidates, and for appropriate referral for transplantation.

(2) Transplantation may be performed either within the VA medical center, at another VA medical center, or in a non-VA facility depending on local circumstances, e.g., available resources, sharing agreements, patient preference and other eligibilities such as Medicare, etc. (see Ch. 7.)

b. VA Satellite Dialysis Unit. A Satellite Dialysis Unit is a designated program in a VA medical center initially intended to provide continued dialysis treatment to stable ESRD patients.

(1) The exact responsibilities carried out by a Satellite Dialysis Unit will depend upon the local needs and the resources at the Satellite as outlined in a formal written affiliation agreement with an affiliated VA dialysis center.

(2) Some Satellite Dialysis Units with the necessary expertise have been authorized to function independently as Interim Dialysis Centers.

4.05 SCOPE OF VA DIALYSIS PROGRAM ACTIVITIES AND ADMINISTRATIVE CONSIDERATIONS

a. Diagnostic Study, Initial Stabilization and Formulation of Treatment Plan, Periodic Review and Reevaluation of Therapy. Dialysis center staff will ordinarily carry out these activities which require multidisciplinary professional expertise.

b. Maintenance Assisted (Full-Care) Dialysis. Patients who are not suitable for home dialysis, or limited and/or self-care dialysis, may require continued assisted full-care dialysis either at a Dialysis Center or satellite. Decisions on mode and location of dialysis treatment will be made by the dialysis center staff.

c. Home Dialysis. Suitable patients and their assistants may be trained to perform dialysis at home.

(1) All VA Dialysis Centers will provide home and/or self dialysis training so that selected patients can continue their dialysis treatments at home; or perform limited and/or self-care dialysis at dialysis centers or satellites, if home dialysis is not feasible. VA encourages home dialysis which permits dialysis facilities to treat additional patients, may offer potential rehabilitation benefits to the patient, and is less costly than continued dialysis in a medical center.

(2) Selection of home dialysis treatment is based on professional determinations of patient suitability by the Dialysis Program staff and consent of the patient.

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(3) In home dialysis, VA provides support services, including supplies and ongoing technical and professional assistance, and placement and installation of dialysis equipment in the patient's home.

(4) Home dialysis equipment will be provided only after there is assurance that the dialysis patient and the attendant are adequately trained, and trained VA personnel are available to provide backup consultation and assistance.

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d. Home Dialysis Attendants. VA provides instruction, and may provide financial support for home dialysis attendants during the instruction period. Such support can be provided either by appointment of the attendant as a "without compensation employee" for the training period, with payment for travel and per diem during the training period, or by use of a contract with the person to be trained.

(1) VA does not encourage the use of paid home dialysis attendants in lieu of family members. However, under extraordinary circumstances, such as when a family member is not available to assist with dialysis care, use of such an attendant may be the most satisfactory alternative for the patient, and preferable to other alternatives from a cost effectiveness standpoint.

(2) In such cases, VA will continue to exercise overall professional responsibility for the patient's care, including assessing the performance capability of the proposed attendant, and periodically monitoring and evaluating the actual performance of the home dialysis attendant.

(3) The VA patient and potential dialysis attendant should be informed that VA does not assume responsibility for the performance of the dialysis attendant or for any untoward effect (such as hepatitis) that the attendants may develop.

(a) The use of a formal agreement for the functioning of the dialysis attendant is encouraged.

(b) The patient and VA-trained attendant might properly be parties to such agreement, which should include:

1. Provision for listing the risks to the patient entailed in dialysis,

2. The responsibilities of the attendant, and

3. The fact that the attendant is not considered to function as an employee of VA.

NOTE: The Office of District Counsel is available to assist in drafting such agreements.

(4) Dialysis attendants may be recruited directly by the patient, with assistance of the Dialysis Unit, or existing community resources may be utilized.

e. Limited and/or Self-Care Dialysis. It has been found that limited and/or self-care dialysis programs are more successful if such activities are carried out separately from the assisted full-care dialysis treatment.

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(1) Selected patients for whom home dialysis is not feasible may be trained to participate actively, to the extent possible, in dialysis treatment provided at a dialysis facility. Thus, only the minimum amount of staff assistance will be necessary.

(2) VA encourages such limited and/or self-care dialysis where appropriate, and additional resources in support of such activities have been provided to many dialysis programs.

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4.06 GUIDELINES FOR VA DIALYSIS UNIT OPERATION

a. Introduction. Operation of a dialysis program requires consideration of various distinct functions including:

(1) Formulation and modification of basic policies and procedures,

(2) Ongoing clinical decision making, and

(3) Conducting quality assurance studies.

NOTE: These functions must be distinguished since the necessary participants and their roles vary.

b. ESRD Committee. A medical center ESRD Committee will be established in each dialysis center to formulate basic policies and procedures, accept patients into the renal replacement program and oversee program activities. The medical center Director will establish the ESRD Committee and approve its membership:

(1) Membership

(a) The Chief, Renal Section, Medical Service, and the Chief, Transplant Section, Surgical Service, will serve on this committee and jointly recommend appointment of the members. The surgeon responsible for surgical problems of ESRD patients will be a member. Non-physician participants including a nephrology nurse, nephrology social worker, and dietitian will be appointed to the committee. At least three physicians will serve on the ESRD Committee, one of whom will serve as chairperson.

(b) Either the Chief, Renal Section or Chief, Transplant Section, may serve as chairperson. In hospitals where only dialysis facilities exist, the Chief, Renal Section, Medical Service, will serve as chairperson of the committee and recommend appointment of the other members.

(2) Responibilities. The ESRD Committee will:

(a) Formulate basic policies and procedures for the dialysis program.

(b) Approve the program's policy and procedure manual.

(c) Accept patients into the renal replacement program. Patient criteria include:

1. The likely quality of life and outcome of dialysis therapy should be considered when formulating medical admission criteria.

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2. Each patient will be considered on an individual basis and no patient should be excluded from the consideration process solely because of a specific diagnosis.

(d) Periodically review clinical care, outcome of therapy, and complications.

(e) Take such actions as are appropriate and/or offer its recommendations to the medical center Director through the Clinical Executive Board to improve ESRD patient care.

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(f) Provide minutes of all meetings; these minutes will include a listing of individuals attending and actions taken.

(3) Since multidisciplinary professional expertise must be available to implement proper ESRD policies, the function for satellite units will ordinarily be carried out at the parent center. If the requirements are met, existing dialysis and transplant committees whether in combination with a university committee or existing totally within VA may be used.

c. Policy and Procedure Manual. Each Dialysis Unit will develop and maintain a manual approved by the ESRD Committee outlining operational objectives, basic policies and approved procedures adopted to assure a high level of patient care:

(1) National guidelines and/or standards developed by recognized agencies and organizations such as the Association for the Advancement of Medical Instrumentation (AAMI)), Center for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA), Surgeon General, and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) should be considered and incorporated as appropriate.

(2) Areas covered in this manual will include:

(a) Admission criteria and procedures to ensure equitable access to ESRD care in accordance with general VA policies and priorities.

(b) Staffing policies for physician and nonphysician personnel in cooperation with other involved services, such a Nursing, Social Work, and Dietetics.

(c) Procedures for ensuring health and safety of patients and staff including:

1. Hepatitis and other infectious disease control, including information, instructions and precautions for home dialysis patients and attendants.

2. Air embolism prevention and treatment.

3. Policy and procedures for dialyzer use (including reuse if any).

4. Standards for dialysate composition, conductivity and temperature.

5. Water purification standards and testing requirements.

6. Blood leak detection and control.

7. Use of monitoring devices, alarms, and other safeguards.

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8. Provisions for emergency medical care.

9. Provisions for power failure, fire, and other nonmedical emergencies.

10. Provisions of social services to help maintain normal social functioning of the patient and the family.

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(d) Procedures for ongoing monitoring and modifying of individual short-term and long-term patient care plans including:

1. Dialysis treatments,

2. Medications,

3. Diet,

4. Suitability for transplant,

5. Psychosocial evaluations,

6. Special treatment, and

7. Continuing care.

NOTE: Such ongoing decision-making will include input from the various professionals involved in the care of the individual patients.

(e) Patient rights, including right to privacy and confidentiality, right to information about medical condition and treatment, and right to participate in selection of treatment options.

(f) Relationship to other VA, or non-VA dialysis, or transplant facilities including affiliated VA satellite unit or center, if any, and to community ESRD organizations.

d. Quality Assurance (QA). QA activities relating to ESRD care including medical audit and utilization review will be integrated into the hospital's overall QA Program.

(1) Recommended elements for dialysis-specific QA include the following:

(a) Qualified physician director;

(b) Functioning ESRD committee;

(c) Written plan including policy and procedure manual;

(d) Monitoring use, for conformance to national guidelines, of:

1. Safeguards,

2. Alarms, and

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3. Monitors and procedures (e.g., relating to water quality, dialysis equipment and supplies, dialyzer reuse and including home dialysis patients);

(e) Review of all deaths and serious complications relating to dialysis;

(f) Periodic review of patient data for maintenance of pre-set targets for clinical, hematological and blood chemistry values;

(g) Participation in local ESRD network (strongly encouraged by the VA Ad Hoc Advisory Group on Renal Disease and Dialysis);

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(h) Periodic review of mortality statistics and comparison to national data and periodically review experience, which may reflect on quality of care, relating to:

1. Staff physician supervision of residents and non-physician staff,

2. Vascular access,

3. Infections,

4. Rehospitalization,

5. Use of consultations,

6. Patient complaints, and

7. Litigation, etc.

(2) Results of ESRD QA studies will be reviewed by the medical center ESRD Committee and appropriate actions undertaken or recommended.

e. Relations of VA ESRD Programs to Community ESRD Organizations and local ESRD Networks

(1) VA data for the United States Renal Data System (USRDS) will be submitted through the local ESRD "Network."

(2) VA medical centers which provide ESRD care to non-VA patients through sharing agreements, and which have been authorized by agreement between VA and the Department of Health and Human Services, and approved as a Medicare ESRD provider will be accorded full membership rights in the local ESRD "network," and will conform to the Medicare Patient Information System, Medical Review Boards, and other requirements with regard to Medicare (but not VA) patient care.

(a) Aggregate VA data, provided for both VA and non-VA patients use, will be included in calculating utilization rates. VA patient data identified by individual and care provided to individual VA patients will not be subject to any mandatory review or external control.

(b) Release of patient data will be in accordance with established policies and procedures governing disclosure of medical information, based upon the Privacy Act of 1974 (5 United States Code (U.S.C). 5552a, and VA confidentiality status (38 U.S.C. 5701 and 7332). NOTE: In this subparagraph the term "patient data" refers to individually identifiable information while the term "aggregate VA data" refers to statistical, nonindividually identifiable information.

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(3) VA medical centers where Medicare patients are not treated, are encouraged to participate voluntarily in local network activities, to the extent possible, in the interest of improved patient care.

(a) As with those VA facilities that do treat Medicare patients, aggregate VA data may be provided, but patient data identified by individual and care provided to individual VA patients will not be subject to any mandatory review or external control.

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(b) Release of patient data will be in accordance with established policies and procedures governing disclosures of medical information, based upon the Privacy Act of 1974 (5 U.S.C. 5552a) and VA confidentiality status (38 U.S.C. 5701 and 7332).

(4) VA employees designated to serve in network activities should avoid participation that would conflict with, or give the appearance of conflicting with, their duties as VA employees. VA Standards of Ethical Conduct and Related Responsibilities, set forth in pertinent in part 38 CFR (Code of Federal Regulations) 0.735-1 through 0.735-23, should serve as guidelines. Further guidance may be sought from the District Counsel.

4.07 FEE-BASIS AND CONTRACT DIALYSIS IN NON-VA DIALYSIS FACILITIES

a. General Policy. Subject to eligibility limits on non-VA provided care, if the required dialysis care cannot be provided directly to a VA patient (such as if the patient lives too far from the VA dialysis unit to return for treatments, or the VA dialysis unit is overtaxed) or by another Federal Government facility under contract with VA, treatments may be provided in non-VA facilities, such as fee-basis or contract dialysis, or by using VA equipment placed in a non-VA hospital by means of a revokable license.

b. Conditions for Provision of Contract/Fee-Basis Dialysis

(1) Fee-basis or contract dialysis for a patient on OPT/NSC status without any other special eligibility for outpatient care supported by VA will not be authorized until full consideration has been given to other possibilities of financial support, such as Medicare and other third-party payers. Where such resources are adequate the NSC patient will be discharged to continue care in a non-VA unit not at VA expense.

(2) Only if it is determined by the facility staff that resources such as Medicare would be clearly insufficient, should approval of fee-basis or contract dialysis care for a veteran who is otherwise eligible for non-VA care be made by the Director of a VA facility with a designated dialysis program.

(3) Any NSC patient placed on contract and/or fee basis dialysis should be reevaluated periodically to determine eligibility (if the patient has become eligible) for other modes of support (such as Medicare) which may permit discharge from the VA program.

(4) A 1-year limitation is placed on OPT/NSC care unless an extension is authorized. Hospitalization of OPT/NSC patients in non-VA facilities (such as for treatment of serious complications during contract dialysis) ordinarily cannot be authorized and paid for by VA.

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(5) No person will be admitted to a VA medical center for the sole purpose of placement on OPT/NSC treatment.

NOTE: VA patients, or potential patients, on contract or fee dialysis should be informed of such limitations.

c. Limitations on Authority for VA Medical Centers Without Dialysis Programs to Authorize Contract or Fee Dialysis

(1) VA medical centers without a dialysis program will not independently authorize fee-basis or contract dialysis care despite clinic of jurisdiction or similar authority,

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except in connection with ongoing contract hospitalization, or in order to provide authorized emergent medical care to veterans eligible for such contract care under provisions of 38 U.S.C. 1703.

(2) Individuals inquiring about care in the VA Dialysis Program will be informed of the limitation on VA payment for care in non-VA facilities, and will be referred to the closest VA Dialysis Program for evaluation of administrative eligibility using established criteria and priorities, and medical assessment.

(3) The VA facility closest to the patient's home, or the clinic of jurisdiction, may carry out administrative aspects of contract or fee-basis dialysis after such treatment is authorized by the Director of a VA medical center having a Dialysis Program.

4.08 REPORTING

a. Automated Management Information System (AMIS) Report. (Segment J-19. 8JD2, RCS 10-0049). Each VA facility with an authorized Chronic Dialysis Program and/or supporting patients on contract/fee-basis dialysis will submit the appropriate AMIS report quarterly summarizing the Dialysis Program activity for the report period. Care must be taken to avoid "double-counting" or other duplicate reporting of the same patients cared for in several VA programs (e.g., a center and its satellite).

b. USRDS. VA has agreed to participate in the USRDS being developed for the National Institutes of Health (NIH) with the cooperation of the Health Care Financing Administration (HCFA). ESRD patient information should be submitted in accordance with instructions.

4.09 BUDGETING CONSIDERATIONS

When fee-basis or contract dialysis is utilized, VA payment will ordinarily be limited to the amount that Medicare has authorized that facility to receive for providing the same service to Medicare beneficiaries. VA may pay 100 percent of the approved charge while Medicare may deduct coinsurance and deductible amounts.

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